

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT
TRANSLATION

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

| | | |
|---|---|---|
| | | Date of mailing (day/month/year) |
| Applicant's or agent's file reference PH-2429-PCT | | FOR FURTHER ACTION See paragraph 2 below |
| International application No. PCT/JP2005/005803 | International filing date (day/month/year) 29.03.2005 | Priority date (day/month/year) 31.03.2004 |
| International Patent Classification (IPC) or both national classification and IPC | | |
| Applicant TORAY INDUSTRIES, INC. | | |

1. This opinion contains indications relating to the following items:

| | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| | |
|--|--------------------|
| Name and mailing address of the ISA/JP | Authorized officer |
| Facsimile No. | Telephone No. |

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/005803

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material
 in written format
 in computer readable form
 - c. time of filing/furnishing
 contained in the international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/005803

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|------------------------------|-----|
| Novelty (N) | Claims 4-8, 13, 14, 16 | YES |
| | Claims 1-3, 9-12, 15, 17, 18 | NO |
| Inventive step (IS) | Claims _____ | YES |
| | Claims 1-18 | NO |
| Industrial applicability (IA) | Claims 1-18 | YES |
| | Claims _____ | NO |

2. Citations and explanations:

Document 1: JP 2003-501631 A (Zeptosens AG), 14 January 2003

Document 2: JP 2001-316298 A (Japan Science & Technology Corp.), 13 November 2001 & EP 1262555 A & US 2003/0092069 A

Claims 1-3, 9-12, 15, 17, 18

Document 1 describes a reagent comprising a vesicle, a polymer molecule and a recognizing element, along with a detection method using this reagent. It describes that the recognizing element binds to the polymer molecule (Claim 3, etc.), and that the polymer molecule binds to the vesicle by means of a membrane protein or other anchor molecule (paragraph 0056), and gives antibodies, antibody fragments, enzymes and membrane receptors as examples of recognizing elements (Claim 2, etc.). It also describes joining an additional label selected from luminescence labels, fluorescent labels and the like to the vesicle (Claim 10, etc.). Moreover, it describes using a waveguide as a sensor platform (Claim 18, etc.).

Since the polymer molecule described in document 1 has the effect of reinforcing the vesicle, it is also capable of forming a vesicle (particle).

Consequently, the inventions of Claims 1, 3, 9-12, 15, 17 and 18 are not novel because they are equivalent to the reagents and detection methods described in document 1.

Claims 4-8

Document 2 describes forming a hollow nanoparticle by using a yeast or the like to express a protein having particle formability, such as a hepatitis B surface antigen.

Since documents 1 and 2 both relate to vesicle-forming technology, adopting those described in document 2 for the polymer molecule and lipid membrane in document 1 would be an obvious matter to a person skilled in the art.

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INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/005803

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Claims 13, 14, 16

Conventionally, various locations have been used for introducing labelling particles when labelling vesicles (see conventional examples in document 1). When introducing the additional label into the vesicle in document 1, binding it to the substance recognizing molecule or polymer or enclosing it inside the vesicle would be an obvious matter to a person skilled in the art.